Elagolix Endometriosis Phase III Trials on Track to Commence in Second Quarter 2012

March 27, 2012

SAN DIEGO, March 27, 2012 /PRNewswire/ -- Neurocrine Biosciences, Inc. (NASDAQ:NBIX) today announced that the United States Food and Drug Administration (FDA) has responded to the Special Protocol Assessment (SPA) filed with the FDA on the design of the Phase III program for elagolix in endometriosis. The FDA comments on the February 2012 SPA filing will be incorporated into the final pivotal trial designs. More importantly, the comments from the FDA are not expected to have an impact on the start of the Phase III clinical program of elagolix for endometriosis which is planned to begin during the second quarter of 2012.

"We are pleased with the FDA's response to the SPA, and are looking forward to the start of the Phase III program next quarter," said Kevin C. Gorman, President and Chief Executive Officer of Neurocrine Biosciences.

Endometriosis is associated with a multitude of symptoms, some of the most common of which include pain related both to menstruation (dysmenorrhea) as well as chronic pelvic pain throughout the menstrual cycle, and infertility. The World Endometriosis Research Foundation estimates that there are over 170 million women worldwide who suffer from endometriosis.

About Neurocrine Biosciences

Neurocrine Biosciences, Inc. is a biopharmaceutical company focused on neurological and endocrine diseases and disorders. Our product candidates address some of the largest pharmaceutical markets in the world, including endometriosis, tardive dyskinesia, uterine fibroids, stress-related disorders, pain, diabetes, insomnia, and other neurological and endocrine-related diseases and disorders. Neurocrine Biosciences, Inc. news releases are available through the Company's website via the internet at http://www.neurocrine.com.

In addition to historical facts, this press release may contain forward-looking statements that involve a number of risks and uncertainties. Among the factors that could cause actual results to differ materially from those indicated in the forward-looking statements are risks and uncertainties associated with Neurocrine's business and finances in general, as well as risks and uncertainties associated with the Company's GnRH program and Company overall. Specifically, the risks and uncertainties the Company faces with respect to the Company's GnRH program include, but are not limited to, risk that elagolix Phase III clinical trials will be delayed or not successfully initiated; risk that elagolix Phase III clinical trials will fail to demonstrate that elagolix is safe and effective for the treatment of endometriosis; risk associated with the Company's dependence on corporate collaborators for clinical development, commercial manufacturing and marketing and sales activities. With respect to its pipeline overall, the Company faces risk that it will be unable to raise additional funding required to complete development of all of its product candidates; risk relating to the Company's dependence on contract manufacturers for clinical drug supply; risks associated with the Company's dependence on corporate collaborators for commercial manufacturing and marketing and sales activities; uncertainties relating to patent protection and intellectual property rights of third parties; risks and uncertainties relating to competitive products and technological changes that may limit demand for the Company's products; and the other risks described in the Company's report on Form 10-K for the year ended December 31, 2011. Neurocrine undertakes no obligation to update the statements contained in this press release after the date hereof.

SOURCE Neurocrine Biosciences, Inc.

Investor Relations of Neurocrine Biosciences, +1-858-617-7600